MedSun
Medical Product Safety Network

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About the MedSun Program:

The MedSun Program, which was launched in 2002 by the U.S. Food and Drug Administration (FDA) Center for Devices and Radiological Health (CDRH), involves the reporting of problems with medical products from a network of approximately 300 hospitals, nursing homes and home health facilities around the United States. MedSun sites work collaboratively with the FDA to assist in detecting, understanding, and sharing information concerning the safety of medical products. MedSun utilizes a secure, on-line system for reporting problems with the use of medical devices. MedSun plays a critical role in FDA's postmarket surveillance efforts.

Those who are interested in having their healthcare facilities join MedSun may contact medsun@fda.hhs.gov or 800-859-9821 for additional information.

Newly Approved Devices

Recently Approved Devices (searchable listing):

https://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/Recently-ApprovedDevices/ucm596872.htm

Premarket Approval Final Decisions:
https://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/PMAApprovals/ucm595393.htm

510(k)s Final Decisions:
https://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/510kClearances/ucm589381.htm

In Brief

As of May 28, 2021

For the FDA Enforcement Report containing the most recent Class I, II and III recalls, go to
http://www.accessdata.fda.gov/scripts/ires/index.cfm

If you see any problems of the type described in these announcements or other device safety issues, please report them through the MedSun reporting system at https://medsun.fda.gov as soon as possible. If you need password information or want to report by phone, please call us at 1-800-859-9821 or e-mail at medsun@fda.hhs.gov.

Recalls and Safety Alerts

Boston Scientific Corporation Recalls VICI VENOUS STENT System and VICI RDS VENOUS STENT System for Potential of Stent Migration
May 21, 2021
Boston Scientific is recalling the VICI SDS and RDS VENOUS STENT Systems after reports indicate that the stents may migrate or move from where they are initially implanted. A migrated stent may require another surgery or catheter procedure to retrieve it, which increases risks to the patient, including possible damage to the blood vessel, heart walls or other organs. If the stent migrates to the heart, it could cause life-threatening injury. There have been 17 complaints and reported injuries related to this issue. No deaths have been reported.

Abbott (formally known as "St. Jude Medical") Recalls Assurity™ and Endurity™ Pacemakers for Potential Moisture Ingress Causing Electrical Short and Reduced Battery Life
May 13, 2021
Abbott (formally known as "St. Jude Medical") is recalling a subset of Assurity and Endurity pacemakers built using specific manufacturing equipment, that were then distributed from April 2015 to February 2019. A small number of devices from that time frame have experienced problems when moisture is able to get inside the device. The moisture can cause an electrical short, that may cause several issues. If the device is unable to deliver pacing, patients may experience slow or irregular heartbeat, fainting, shortness of breath, tiredness, dizziness, or discomfort. Finally, if the system does not relay accurate information via telemetry, medical providers may not know to provide treatment. There have been 135 complaints, 135 injuries, and no deaths reported for this issue.

Medtronic, Inc. Recalls Instructions for Use and Patient Manual for HeartWare HVAD System to Update Information about Carrying Case, Driveline Cover, and Controller Power-Up Issues
May 12, 2021
Medtronic is recalling their HeartWare HVAD System to provide updated Instructions for Use (IFU) and Patient Manual (PM) due to safety issues with (1) Carrying Cases, (2) Driveline Cover Orientation and; (3) Controller Power-Up Sequence. If using the HVAD system and (1) the carrying case breaks and the driveline pulls out of the controller as it drops, or (2) the driveline disconnects from backwards driveline cover orientation; or (3) a controller exchange is performed unnecessarily due to confusion of start-up behavior as a "red alarm" battery failure, this may cause serious patient harm, including death. There has been 1 death and 64 injuries reported to the FDA for these issues.

FDA Safety Communication - Antibody Testing Is Not Currently Recommended to Assess Immunity After COVID-19 Vaccination

FDA is reminding the public and health care providers that results from currently authorized SARS-CoV-2 antibody tests should not be used to evaluate a person's level of immunity or protection from COVID-19 at any time, and especially after the person received a COVID-19 vaccination. While a positive antibody test result can be used to help identify people who may have had a prior SARS-CoV-2 infection, more research is needed in people who have received a COVID-19 vaccination. Currently authorized SARS-CoV-2 antibody tests have not been evaluated to assess the level of protection provided by an immune response to COVID-19 vaccination. If antibody test results are interpreted incorrectly, there is a potential risk that people may take fewer precautions against SARS-CoV-2 exposure. Taking fewer steps to protect against SARS-CoV-2 can increase their risk of SARS-CoV-2 infection and may result in the increased spread of SARS-CoV-2.

Recommendations for Health Care Providers:

- At this time, do not interpret the results of qualitative, semi-quantitative, or quantitative SARS-CoV-2 antibody tests as an indication of a specific level of immunity or protection from SARS-CoV-2 infection after the person has received a COVID-19 vaccination. While a positive antibody test can indicate an immune response has occurred (seroconversion), and failure to detect such a response may suggest a lack of immune response, more research is needed. Currently authorized SARS-CoV-2 antibody tests are not validated to evaluate specific immunity or protection from SARS-CoV-2 infection. SARS-CoV-2 antibody tests should be ordered only by health care providers who are familiar with the use and limitations of the test.

- Be aware that vaccines trigger antibodies to specific viral protein targets. For example, currently authorized COVID-19 mRNA vaccines induce antibodies to the spike protein and not to nucleocapsid proteins that are likely detected only after natural infections. Therefore, COVID-19 vaccinated people who have not had previous natural infection will receive a negative antibody test result if the antibody test does not detect the antibodies induced by the COVID-19 vaccine. If you are considering antibody testing in vaccinated individuals, follow the Centers for Disease Control and Prevention's guidelines for antibody testing.

To read the full safety communication and all of FDA's recommendations for health care providers please visit FDA's website.

FDA Letter to Health Care Providers - Stop Using Certain Syringes and Needles with Needle Safety Devices Manufactured by HAIOU

FDA is recommending health care facility risk managers, procurement staff, and health care providers stop using certain syringes and needles with needle safety devices manufactured by Guangdong Haiou Medical Apparatus Co., LTD. (HAIOU) at this time while FDA continues our evaluation.

The FDA received information about quality issues, including certain HAIOU needles detaching from the syringe after injection and other needle safety device failures. These device failures have been reported for the following HAIOU syringe and needle configurations (combinations of syringes and needles with needle safety devices):

1mL syringe with 25G x 1-inch needle

1mL syringe with 23G x 1-inch needle

Recommendations:
The FDA recommends health care facility risk managers, procurement staff, and health care providers:

- Stop using and remove from your inventory the 1mL syringe with 25Gx 1-inch needle and the 1mL syringe with 23G x 1-inch needle configurations (combinations of syringes and needles with needle safety devices) manufactured by HAIOU until further notice. Users and facilities that decide to dispose of applicable unused product should follow facility processes for sharps disposal.

- Do not purchase these HAIOU syringes and needle configurations until further notice.

- Be aware that these syringes and needle configurations may be available as individual units or may be included as part of a kit. ◦Currently, we are not aware of concerns with other products (such as gloves, alcohol pads, etc.) that may be provided in kits alongside the 1mL syringe with 25Gx 1-inch needle and the 1mL syringe with 23G x 1-inch needle configurations, but these HAIOU syringes and needle configurations should not be used.

- Report any issues with the quality or performance of these devices to the FDA.

To read the full letter and all of FDA's recommendations for health care providers please visit FDA's website.

HIGHLIGHTED REPORTS

The reports that follow represent a cross section of device-related events submitted by MedSun Reporters during May 2021. The reports are displayed within clinical specialty areas based on analysis of the information submitted. The reports are presented as submitted by MedSun Representatives and in some instances have been summarized and/or edited for clarity.

A database of all MedSun reports can be found at:

http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/medsun/SearchReportText.cfm

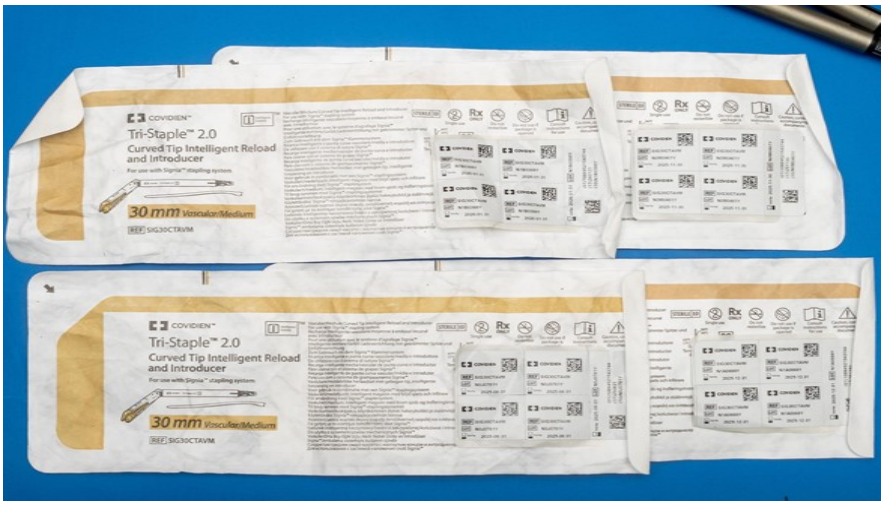
 Special Note:

The lollipop icon distinguishes highlighted reports that describe medical device events involving neonatal or pediatric patients, or those events involving a medical device that is indicated for use in neonatal and pediatric patient populations. FDA defines pediatric patients as those who are 21 years of age or younger (that is, from birth through the twenty-first year of life, up to but not including the twenty-second birthday) at the time of the diagnosis or treatment.

Device	Manufacturer	Problem
Applicator, Absorbent Tipped, Sterile Brand: Specimen Collection Swab – Nasopharyngeal Model#: SW0102 Lot #: 062820 Cat #: SW0102	Typenex Medical, Inc.	Patient was being tested for COVID, and speciman collection swab broke off at the score line while still in his nose. Patient was seen by provider that was in the clinic and swab was easily removed with sterile forceps. patient stated that he was feeling well after and specimen was collected. It was reported they received new swabs that are "paper" not plastic. While they are easier to break into the testing tube, these new swabs bend very easy. Writer opened swab and applied little to no pressure above the scoring and broke easily. This appears to be an equipment issue verses an operator.

Device	Manufacturer	Problem
Index-generating Electroencephalograph Software Brand: Bispectral Index (Bis) Monitor Other #: VT32924	Covidien	At the beginning of a case, during routine patient monitoring, the BIS monitor connected to the patient made a loud "pop" and began smoking vigorously. The procedural team quickly disconnected the monitor and removed it from the room. The monitor then caught fire and was subsequently extinguished via fire extinguisher.
Oximeter Brand: Nellcor Maxfast Oximax Forehead Spo2 Sensor, Adult Model#: MAXFAST Lot #: 210810173H Cat #: MAXFAST	Covidien LP	Patient had a forehead SpO2 sensor with headband on their forehead for less than 24 hours. When the nurse removed the sensor for rotation, nursing noted a deep tissue pressure injury on the forehead. The forehead sensor was left off and an ear sensor was used instead. This is the first of two recent events whereby nursing has reported deep tissue injuries related to the use of the forehead SpO2 sensors with headband. It was recommended to nursing by Education that they rotate the sensors frequently or to not use the headband as it adds extra pressure to the sensor. Nursing has provided feedback recommending that the manufacturer improve/enhance the instructions for use on the product, frequent rotation of the sensors (every two hours or more frequently) on the headband, and to rotate device on the sensor sticker. The forehead SpO2 sensor with headband is generally used when unable to get an oxygen saturation level on the finger. Nurses are encouraged also to use an ear sensor as an alternative. Because we have had two similar events, we have pulled this product from the ICUs.
Device 1: System, Endovascular Graft, Aortic Aneurysm Treatment Brand: Ovation Ix Iliac Stent Graft Model#: Iliac Extension Cat #: TV-EX282845-J **Device 2: System, Endovascular Graft, Aortic Aneurysm Treatment** Brand: Ovation Ix Iliac Stent Graft Model#: Iliac Limb Lot #: (not provided) Cat #: TV-IL1428100-J	Trivascular, Inc. Trivascular, Inc.	It is difficult for health care providers to know/notice from the stent graft packaging, of the TriVascular® Ovation Prime® Abdominal Stent Graft System with the Ovation iX Iliac Stent Graft, that it is a tapered (TS) stent. The stent was placed during an urgent situation. The description at the top of the package is very similar to a nontapered (NTS) stent (pictures available). The package on the left (Catalog # TV-EX282845-J) is a NTS stent and the right (Catalog # TV-IL1428100-J) is a TS stent. When reviewing the size, it was easily missed, the picture also does not note a taper in the stent.

Device	Manufacturer	Problem
Occluder, Patent Ductus, Arteriosus Brand: Amplatzer™ Lot #: 7754442 Cat #: 9-PDA-003 	AGA Medical Corporation	A 5 French AMPLATZER sheath was advanced antegrade across the patent ductus into the descending aorta. A 5/4 AMPLATZER duct occluder was inserted into the sheath and advanced into the end of the sheath. The sheath was pulled back, and the retention disc was advanced out the end of the sheath. The entire apparatus was pulled back into the ductus. Multiple selective aortograms were performed to assess device position. Following appropriate positioning of the device, the device was released and the delivery system was removed. Shortly after release, the device spontaneously embolized into the descending aorta. A pigtail catheter was used to maintain stability of the device in the descending thoracic aorta. The 5 French AMPLATZER sheath was exchanged for a 6 French AMPLATZER sheath, which was advanced into the descending aorta. Using a variety of retrieval devices, attempts at antegrade retrieval of the device were made, but due to the anatomy of the ductus, this was not possible. Next, catheter manipulations were performed, and the device was repositioned within the ductus. Follow-up angiograms demonstrated the device in reasonable position within the ductal ampulla with a small residual shunt through the device. However, due to the original embolization of the device it was not felt this position was stable and surgical intervention was required. The decision was made to proceed with surgical patent ductus arteriosus (PDA) ligation and removal of the occluder. Per cardiothoracic surgeon, chest entered through 4th intercostal space. Surgeon found a large tortuous PDA, and noted that the occluder device could be felt in the aorta at the isthmus, but was not occluding flow, and the lower extremity arterial pressure was normal. Two LIGACLIP ligating clips were placed across the PDA to close it. The aorta was then mobilized proximal and distal to the PDA. A heavy silk tie was placed around the aorta proximal and distal to the duct to get control. The aorta was then clamped proximal and distal at the site of the circumferential loose silk ties. A small incision was made transversely in the aorta at the isthmus, and the device was immediately visible and removed through the incision. The aortotomy was then closed with a 5-0 prolene suture. The aorta was de-aired just prior to clamp removal by removing the distal clamp first and allowing a small amount of bleeding and de-aiing of the aorta. Once the suture was tied, the proximal clamp was removed. Echocardiogram the following day showed flail anterior tricuspid leaflet secondary to ruptured chordae, likely due to catheter manipulation during cardiac cath, resulting in moderate tricuspid insufficiency. The ventricular function of the patient was normal without residual PDA. Pediatric patient recovered quickly, and was discharged home 2 days later.

Device	Manufacturer	Problem
Device 1: Staple, Implantable Brand: Endo Gia Ultra Model#: EGIAUSHORT Lot #: P1B1253 Cat #: (17)260131 (10)P1B1253	Covidien LP	Once the pulmonary artery was freely dissected, the superior segmental artery was encircled in a vessel loop placed around it. Only one-third of the staples fired resulting in incomplete division of the artery. This necessitated control of bleeding. So, an additional vessel loop was placed around the remaining vessel. Another vascular staple load was fired and the same issue occurred with only one-third of the staples firing with inability of the operator to move the staples any further. A clamp was placed along the proximal aspect of the pulmonary artery. The stapler was removed and again bleeding was controlled. A stapler device from a different manufacturer was used to complete the pulmonary artery division. If the third device had not deployed staples successfully, the patient would have exsanguinated. All personnel were experienced in the use of these products. If the staple load had not been correctly connected, the stapler would not have fired. However, we have been made aware that there is about a 90% chance that if the load is not connected appropriately it will fire. The loading issue seems to be a possible design defect. Please see pictures below: 
Device 2: Staple, Implantable Brand: Endo Gia Ultra Model#: EGIAUSHORT Lot #: P1B1430 Cat #: (17)260131 (10)P1B1430	Covidien LP	
Device 3: Staple, Implantable Brand: Tri-staple 2. 0 Model#: SIG30C-TAVM Lot #: N1B0398Y Cat #: SIG30C-TAVM	Covidien LP	
Device 4: Staple, Implantable Brand: Tri-staple 2. 0 Model#: SIG30C-TAVM Lot #: N0M0461Y Cat #: SIG30C-TAVM	Covidien LP	
Device 5: Staple, Implantable Brand: Tri-staple 2. 0 Model#: SIG30C-TAVM Lot #: N0J0781Y Cat #: SIG30C-TAVM	Covidien LP	

Device	Manufacturer	Problem
Surgeon's Gloves Brand: Medichoice Polyisoprene Surgical Gloves (Distributed By Owens And Minor) Lot #: 2010525704 Cat #: SGL95085	Ansell Healthcare Products, LLC	Patient underwent cataract surgery and developed Toxic Anterior Segment Syndrome (TASS) post procedure. Surgical Technician and Surgeon noticed a difference in texture of the surgical gloves used in this particular case. The difference in texture raised concerns of surgical gloves possibly containing a powdered substance. The gloves in question are MediChoice Polyisoprene Surgical gloves REF #SGL95085 with a lot number 2010525704. All Gloves with this specific lot number were pulled from the Operating Room and isolated.
Set, Administration, Intravascular Brand: Cadd Medication Cassette Model#: 21-7302-24 Lot #: 4076292	Smiths Medical, Inc.	Patient was connected to an ambulatory infusion pump (CADD) containing chemotherapy (5FU). Patient reported to Cancer Center for anticipated disconnection. Patient reported CADD pump alarmed that the infusion was complete 4 hours before it was scheduled to be completed. Patient called MD on call between 6 am & 7 am and was advised to come to the Cancer Ctr. when it opened at 9 am. When patient arrived, the pump stated patient received 78 ml and that 12 ml remains to be infused, but the medication bag was completely collapsed / empty. Subsequently we have had similar cases reported by 7 other patients. We have pulled all of the affected pumps from service and are working with Infusystem (Pump manufacturer) and Smiths Medical (cassette / tubing manufacturer) to trouble shoot and find a resolution to this problem.
Drills, Burrs, Trephines &Accessories (Compound, Powered) Brand: Codman Disposable Perforator 14mm Model#: REF 26-1221 Lot #: J74X88 Cat #: REF 26-	Codman and Shurtleff, Inc.	During a Deep Brain Stimulator case, during the use of the perforator, a perforator used for the procedure didn't stop (even though design was supposed to stop drilling after penetration) and caused a dural and cortical tear. Per doctor there was no permanent long-term damage to the patient. The device was sent to the company for examination.

Device	Manufacturer	Problem
Apparatus, Exhaust, Surgical Brand: Neptune Model#: 0703001000 Cat #: 0703001000	Stryker Corporation	While operating we smelled a burning smell, we checked the patient and he was fine, so we called the charge nurses to come help us search the room to locate the source. While searching, we found the smell to be heavy in the area around the surgical field and noticed that the suction was powered off and had been on throughout the case. We called biomed and he came to the room and removed the suction from the operating room. Upon inspection biomed found the circuit board to be melted and burnt.

Links to FDA/CDRH Databases and Other Information Sources

Device Listing: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRL/rl.cfm
This database contains a listing of medical devices in commercial distribution by both domestic and foreign manufacturers.

Establishment Registration: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRL/rl.cfm
This is a searchable database of U.S. and foreign establishments engaged in the manufacturer, preparation, propagation, compounding, assembly, or processing of medical devices for U.S. distribution. Note: This database is updated once a month.

Human Factors Website: http://www.fda.gov/medicaldevices/deviceregulationandguidance/humanfactors/default.htm. This site provides information on human factors design, testing and use considerations for healthcare professionals, manufacturers and consumers.

Luer Misconnections Website:
http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/TubingandLuerMisconnections/default.htm
This site provides information for healthcare professionals about hazards that occur when different device delivery systems are mistakenly connected to each other facilitated by the use of Luer connectors.

MAUDE (Manufacturer and User Facility Device Experience): http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/search.CFM
MAUDE data represents reports of adverse events involving medical devices. The data consists of all voluntary reports since June 1993, user facility reports since 1991, distributor reports since 1993, and manufacturer reports since August 1996.

Medical Device Safety Website: http://www.fda.gov/medicaldevices/safety/default.htm
One-stop for safety information with links to published safety tips and articles, archived patient safety news programs, safety alerts, recalls, and a link to report a device-related problem.

MedSun Website: https://medsun.fda.gov/
This site provides patient safety information via current and past issues of the MedSun newsletter, educational materials, and search capability for MedSun adverse event reports.

Premarket Notifications [510(k)]: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm
This database of releasable 510(k) s can be searched by 510(k) number, applicant, device name or FDA product code. Summaries of safety and effectiveness information are available via the web interface for more recent records. The database is updated monthly.

Premarket Approvals (PMA): http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pma.cfm
This database of premarket approvals of Class III devices may be searched by a variety of fields and is updated on a monthly basis.

Product Classification: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD/classification.cfm
This database can be used to determine the classification of a device and the regulations it is subject to.

Warning Letters: http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/default.htm
This database contains the most recent manufacturer warning letters.

To access additional newsletter articles, including a selection of recent MedSun Reports and product-related and patient safety-related information, go to www.fda.gov/medsun

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